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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,240	03/25/2004	Shoji Miyazaki	55220/845	6687

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1795	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,240	MIYAZAKI ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/03/2009 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *45 and 47-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45 and 47-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/06/2009 and 02/03/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *IDS of 8/15/2008; 02/02/2009; and 10/14/2008*.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of February 03, 2009 does not render the application allowable. In regard to the double-patenting rejections the PTO paralegal assigned to process them was unable to do so because the signing attorney, Craig Arnold, is not of record. Also, since Applicant's claims are not patentably distinct from the claims of Miyazaki and Miyazaki II the double-patenting rejections are maintained, except for claim 46, which has been cancelled. In regard to the prior art rejections, as discussed in the new rejections of claims 45 and 47 below, WInarta as modified by Kawanaka also discloses the new limitations to these claims.

Status of the Rejections pending since the Office action of October 17, 2008

2. All of the double-patenting rejections are maintained, except for claim 46, which has been cancelled.

3. All of the rejections under 35 U.S.C. 103(a) are withdrawn, but have been rewritten below in light of Applicant's amendment.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 45-48, 51, 55-60, and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 ("Winarta") in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka").

Addressing claim 45, Winarta discloses a biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter

electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61), and

each of the electrodes comprising a measuring part (exposed by cutouts W1, R, or W2 in Figure 2 and col. 05:45-46) for outputting of an electrical change resulting from a reaction between the sample liquid and the reagent layer (col. 06:22-35).

WInarta does not mention whether the biosensor has a correction part for having information of correction data which correspond to output characteristics of the biosensor, providing one or a plurality of a second type of slits dividing the electrode part, and the correction data can be discriminated by a measuring device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define a correction part of the electrode part at the rear end of the biosnesor, which would be a second type of slits. See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32; and col. 31:44-49 (note the a the pattern of the correction part may be made by cutting). The correction part for having information of correction data which correspond to output characteristics of the biosensor, providing one or a plurality of a second type of slits dividing the electrode part, and the correction data can be discriminated by a measuring device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes. See col. 02:45 – col. 07:19; col. 09:53-62; and col. 21:46-67. It would have been

obvious to one with ordinary skill in the art at the time of the invention to provide a second type of slits for dividing the electrical conductive layer to define a correction part of the electrode part as taught by Kawanaka in the invention of WInarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08. Applicants should note that even though Kawanaka already discloses cutting the electrode part to form the correction part, which implies forming slits, especially in light of Figures 20, 22, 24, 28, and 32, it would have also been obvious to do so because the base reference Winarta already teaches scribing or scoring the conductive layer to pattern the electrode part as desired (col. 07:58 – col. 08:01). Also, although Winarta as modified by Kawanaka already discloses that the correction data can be discriminated by a measuring device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes, even if Applicant can somehow show that this is not the case, this is only an intended use of which the correction part in WInarta as modified by Kawanaka is capable as such discrimination is performed by a device separate from the biosensor (see Applicant's Figures 16 and 17. Also compare Applicant's Figures 9(a)-(c) and 10(a)-10(h) with Kawanaka's Figures 10, 22, 24, 28, and 32).

Addressing claim 47, Winarta discloses a biosensor for quantifying a substrate included in a sample liquid (col. 01:01-20) comprising:

a first insulating support (20) and a second insulating support (50);

an electrode part comprising at least a working electrode and a counter electrode (col. 10:36-40 – note that since there is not a separate counter electrode one with ordinary skill in the art would understand that the reference electrode also functions as a counter electrode);

a specimen supply path (112) for introducing the sample liquid to the electrode part (col. 10:63 – col. 11:02); and

a reagent layer employed for quantifying the substrate included in the sample liquid (col. 10:41-53 and col. 09:14-26),

where the electrode part, the specimen supply path, and the reagent layer are situated between the first insulating support and the second insulating support (Figure 2),

the specimen supply path being provided on the electrode part, and the reagent layer being provided on the electrode part in the specimen supply path, respectively (Figure 2 and col. 10:41-43),

the electrode part being dividedly formed by a first type of slits provided on an electrical conductive layer which is formed on the whole or part of an internal surface of

one or both of the first insulating support and the second insulating support (Figure 2 and col. 07:58-61), and

each of the electrodes comprising a measuring part (exposed by cutouts W1, R, or W2 in Figure 2 and col. 05:45-46) for outputting of an electrical change resulting from a reaction between the sample liquid and the reagent layer (col. 06:22-35).

WInarta does not mention whether the biosensor has a correction part for having information of correction data which correspond to output characteristics of the biosensor, providing one or a plurality of a second type of slits dividing the electrode part, and the correction data can be discriminated by a measuring device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define a correction part of the electrode part at the rear end of the biosensor, which would be a second type of slits. See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32; and col. 31:44-49 (note the a the pattern of the correction part may be made by cutting). The correction part for having information of correction data which correspond to output characteristics of the biosensor, providing one or a plurality of a second type of slits dividing the electrode part, and the correction data can be discriminated by a measuring

device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes. See col. 02:45 – col. 07:19; col. 09:53-62; and col. 21:46-67. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a second type of slits for dividing the electrical conductive layer to define a correction part of the electrode part as taught by Kawanaka in the invention of WInarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed (calibration data) can be conveyed to the measuring apparatus. See col. 05:44 – col. 06:08. Applicants should note that even though Kawanaka already discloses cutting the electrode part to form the correction part, which implies forming slits, especially in light of Figures 20, 22, 24, 28, and 32, it would have also been obvious to do so because the base reference Winarta already teaches scribing or scoring the conductive layer to pattern the electrode part as desired (col. 07:58 – col. 08:01). Also, although Winarta as modified by Kawanaka already discloses that the correction data can be discriminated by a measuring device employing the biosensor on the basis of whether or not there is the second type of slit for dividing the measuring part and the correction part in each of the electrodes, even if Applicant can somehow show that this is not the case, this is only an intended use of which the correction part in WInarta as modified by Kawanaka is capable as such discrimination is performed by a device separate from the biosensor (see Applicant's Figures 16 and 17. Also compare Applicant's Figures 9(a)-(c) and 10(a)-10(h) with Kawanaka's Figures 10, 22, 24, 28, and 32).

WInarta as modified by Kawanaka also disclose providing one or a plurality of a third type of slits for dividing the electrical conductive layer to define an area of the electrode part in as much as the first and third types of slits are arbitrary designations. Applicant's specification (pre-grant publication 2004-0178067 paragraph [0175]) identifies slits 43a and 43b as first slits yet slits 44a and 44b, which are parallel to slits 43a and 43b, are identified as third slits. Alternatively, the slits that form the electrode for avoiding potential static problems in WInarta can be third type of slits. See WInarata col. 07:63 – col. 08:01.

Addressing claim 48, for the additional limitations of this claim see Figure 2 in WInarta and Figures 8, 9, 20, 22, 24, and 28-32 in Kawanaka.

Addressing claim 51, for the additional limitations of this claim see Figure 2 and col. 07:58-61 in Winarta.

Addressing claim 55, for the additional limitations of this claim see Figure 2 in Winarta and note spacer 40.

Addressing claim 56, for the additional limitation of this claim see Figures 1 and 2; col. 11:09-11; and col. 11:39-41 .

Addressing claim 57, for the additional limitation of this claim note element 52 in Figure 2.

Addressing claim 58, as for the reagent layer being formed by dripping a reagent, this is a product-by-process limitation that does not patentably distinguish the dispensed reagent of Winarta, which was probably "dripped", from Applicant's reagent, and

As for a fourth type of slits, these can be taken to be the three angled segments of slit 28 at the front end of the biosensor shown in Figure 2, as they are not for forming electrodes, but means to "avoid potential static problems which could give rise to a noisy signal" – col. 07:63 to col. 08:01. They are also provided around a position where the reagent is dripped (Figure 2).

Addressing claim 59, WInarta only discloses linear slits. See Figure 2 in WInarta. However, to make the second type of slits arc-shaped is just a mere arbitrary change in shape, unless Applicant shows that the slit shape is significant. See MPEP 2144.04.IV.B.

Addressing claim 60, WInarta does not disclose providing a third type of slits and a fourth type of slits formed by processing the electrical conductive layer by a laser.

Kawanaka discloses a concentration measuring apparatus, test strip for the concentration measuring apparatus, biosensor system and method for forming terminal on the test strip. The test strip is substantially planar and comprises laminated layers and a type of slits for dividing the electrical conductive layer to define an area of the electrode part, which would be a third type of slits and a fourth type of slits (the third type of slit conveys information on what analyte the biosensor is configured to detect - see rejection of claim 56 above). See the title, abstract, Figures 33, 34, 8, 9, 20, 22, 24, and 28-32. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a third type of slits for dividing the electrical conductive layer to define an area of the electrode part and a fourth type of slits as taught by Kawanaka in the invention of WInarta because as taught by Kawanaka then the information of correction data regarding the test strip as claimed can be conveyed to the measuring apparatus. For example, the third slits can indicate the particular analyte the test strip is configured to measure and the fourth slits can indicate calibration date. See col. 02:45 – col. 05:07 and col. 05:44 – col. 06:08.

As for the slits being formed using a laser, this is a product-by-process limitation that does not further patentably limit the slits. In any event Winarta discloses forming slits in the electrically conductive material using a laser. See col. 04:15-30 and col. 07:54-63.

Addressing claims 62-65, for the additional limitations of these claims see col. 07:44-51; col. 08:26-52; and col. 09:14-40.

6. Claims 49, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winarta et al. US 6,287,451 B1 ("Winarta") in view of Kawanaka et al. US 6,599,406 B1 ("Kawanaka") as applied to claims 45, 47, 48, 51, 55-60,and 62-65 above, and further in view of Ikeda et al. US 5,582,697 ("Ikeda").

Winarta does not disclose the electrode part further comprising a detecting electrode; however, WInarta does disclose providing a third electrode, W2, that could also function as a detecting electrode. As shown by Ikeda a third electrode located at the end of a capillary channel in a biosensor test strip could be used as a detecting electrode in addition to alternatively being involved in the actual sample measurement (abstract and Figure 1).

For claim 53 note that WInarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. Since electrode W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) the sum of the area for electrode "R" (the

counter/reference electrode) and the area of W2 (detecting /pseudo working electrode) will necessarily be greater than that of the W1 (the working electrode).

For claim 54 note that WInarta discloses that the cutouts for the working electrodes have the same area and that the cutout for the counter/reference electrode may be the same or larger than that for the each working electrode. Since electrode W2 is being construed as a detecting electrode (actually a dual purpose pseudo working electrode/ detecting electrodes) it may have the same area as the counter electrode ("R").

7. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over WInarta in view of Kawanaka as applied to claims 45, 47, 48, 51, 55-60,and 62-65 above, and further in view of Fujiwara et al. US 6,004,441 ("Fujiwara").

WInarta as modified by Kawanaka does not appear to mention the possible widths of the silts; however, as noted in the rejection of claim 60 WInarata does disclose using a laser to form the slits.

Fujiwara discloses making slits in a metal film to make electrodes or a test strip type biosensor. The slits are made using a laser and be 70 microns (=0.07mm) in width. See the abstract and col. 02:52-59. In light of Fujiwara Applicant's claimed slit width range of 0.005 mm to 0.3 mm is just a matter of scaling the biosensor to the

expected volume range of sample, by , for example, making smaller more closely spaced electrodes for smaller expected sample volumes.

Final Rejections

8. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
May 4, 2009